

Department of Home Affairs
Commonwealth Government
6 Chan Street
BELCONNEN ACT 2617

November 27, 2020

Dear Sir/Madam,

Submission from Medicines Australia to the Department of Home Affairs: Protecting Critical Infrastructure and Systems of National Significance: Exposure Draft Security Legislation Amendment (Critical Infrastructure) Bill 2020

Thank you for the opportunity to provide comment on the Exposure Draft Security Legislation Amendment (Critical Infrastructure) Bill 2020 (the Bill).

Medicines Australia leads the research-based pharmaceutical industry in Australia. Our members discover, develop, manufacture medicines and vaccines that bring health, social and economic benefits to Australia. These members invest in Australian medical research and take local discoveries and developments to the world.

Medicines Australia works with governments, together with the life sciences, research and healthcare sectors, to support a secure and enabling commercial environment for the development and delivery of medicines to Australian patients. This includes ensuring that legislative frameworks are fit for purpose and do not add unnecessary and costly regulatory burdens.

In this context, Medicines Australia, while supportive of efforts to strengthen Australia's security and economic resilience, is cautious about the broadly defined remit of this Bill. Our members already work hard to maintain the highest security standards to ensure patient needs are met and protect company data and associated intellectual property. We would not wish to see the introduction of government powers that inadvertently impede the ability of companies to continue usual business operations.

We note that the Bill proposes a broad definition for critical infrastructure assets in the health and research sectors, namely those assets, systems or networks involved in the provision of health care, production of medicines, medical supplies and medical research. These definitions capture all Medicines Australia members and their research and development partners and, therefore, could draw them into a future framework developed under sector specific rules or under a declaration as a critical asset by the Minister for Home Affairs.

We also note that private and public hospitals are explicitly prescribed in the Bill as critical infrastructure assets. This would also likely impact Medicines Australia members who conduct clinical trials at these and other related institutions, including educational institutions, which support research and development. It would be an undesirable outcome if, due to onerous security requirements, clinical trials were delayed, thereby denying patients access to innovative life-saving medical treatments.

Medicines Australia and our members propose to work closely with the Department of Home Affairs in the development of the sector-specific rules that will underpin this Bill. It is important that any health, medicines, or research-related rules be fit for purpose and do not unnecessarily increase regulatory burdens or the costs of running what has proven, especially throughout COVID-19, to be a secure and

resilient industry. This includes safeguarding against any unintended consequences such as the costs associated with increasing security measures by other parts of the life sciences and healthcare sectors being passed on to industry.

Medicines Australia also recommends that the government consider how they will support public and private institutions in transitioning to implementing potentially higher security obligations. This could entail increased funding support to those affected public institutions, in particular, as well as how the new obligations could support the government's efforts to enable and incentivise business to work more efficiently and securely in Australia. We do not wish to see business development and subsequent economic growth stifled by unnecessarily burdensome and costly regulations at a time when industry is working hard to help rebuild a healthy and economically strong Australia in a post-pandemic world.

The pharmaceutical industry, represented by Medicines Australia looks forward to thorough consultation and participation as the Department proceeds to the next stages of this project.

The Medicines Australia contact for this project is Peter Komocki, Manager, Industry and Regulatory Policy (email: pkomocki@medaus.com.au).

Yours sincerely



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Medicines Australia